REMARKS

Upon entry of the present amendment, claims 1, 2, 4, 7, 9-12, 15, 17, 19-20, 23-30 and 32-34 are pending. Claims 1, 4, 7, 9, 12, 15, 17, 20, 30 and 32 have been amended as will be discussed below. Claims 5, 6, 13, 14, 18, 21, 22, 33, and 34 have been cancelled. Claims 3, 8, 16, 31, and 34-67 were cancelled in prior amendments. Support for the amendments to the claims can be found throughout the specification and claims as originally filed and there is no new matter added as a consequence of the amendments. Applicants reserve the right to continue prosecution of the cancelled subject matter in continuation applications.

Information Disclosure Statement

Applicants have reviewed the PTO 1449 forms submitted previously, which list references considered by the Examiner, and noted that there is one reference listed on the PTO 1449 form, mailed December 19, 2001, that is not initialed. Applicants submit herewith a copy of the PTO 1449 form returned to applicant with the Office Action mailed December 4, 2002. Please initial and consider the reference listed at the top of page 2 of the PTO 1449. For the Examiner's convenience, applicants also submit a copy of the cited reference, Ranieri et al. ("Dendritic cells transduced with an adenovirus vector encoding Epstein-Barr virus latent membrane protein 2B: a new modality for vaccination, " J. Virol. 1999, 73:10416-10425.)

The Rejections under 35 U.S.C. § 112, ¶1 Should Be Withdrawn

The Examiner has maintained the rejection of claims 4-6, 12-14, and 32-34 under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, wherein the oligodeoxyribonucleotide is SEQ ID NO:1 and further comprising an adenoviral vector encoding CTLA4Ig, allegedly does not reasonably provide enablement for an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector.

In response, claims 4, 12, 20 and 32 have been amended to refer to an adenoviral vector encoding CTLA4Ig. Support for the amendments to the claims can be found in the specification at page 36, lines 15-17 and page 38, line 18 to page 39, line 12). Accordingly, claims 5, 6, 13, 14, 33 and 34 have been cancelled.

The Examiner has also maintained the rejection of claims 15 and 17-29 under 35 U.S.C. § 112, first paragraph. The Examiner alleges that the specification is enabling for a method of enhancing tolerogenicity in a mammalian transplant host, comprising the intravenous administration of an isolated tolerogenic dendritic cell comprising an oligodeoxyribonucleotide, where the oligodeoxyribonucleotide is SEQ ID NO:1, further comprising an adenoviral vector encoding CTLA4Ig, and further comprising incubating said isolated tolerogenic dendritic cell in the presence of GM-CSF. However, the Examiner alleges that the specification does not reasonable enablement for a method of enhancing tolerogenicity in a mammalian host with an inflammatory related disease or arthritis, comprising any route of administration of an isolated

tolerogenic dendritic cell comprising an oligodeoxyribonucleotide having one or more NFκB binding sites, further comprising a viral vector, further comprising incubating said isolated tolerogenic dendritic cells in the presence of one or more cytokines, TGFβ, FK 506 or cyclosporine.

In response, applicants submit that support for a method of enhancing tolerogenicity in a mammalian host with inflammatory related disease or arthritis can be found in the specification at page 17, para.00047; page 22, para. 00059; page 23-24, para. 00063. Support for "any" route of administration of an isolated tolerogenic dendritic cell can be found in the specification at page 21, para. 00057. Support for the administration of TGFβ can be found in the specification at page 7, para. 00016; page 19, para. 00052. Support for the administration of FK 506 can be found in the specification at page 29, para. 00053. Support for the administration of cyclosporine A can be found in the specification at page 29, para. 00053.

With regard to enablement for a method of enhancing tolerogenicity in a mammalian host comprising administration of an isolated tolerogenic dendritic cell comprising, *inter alia*, a viral vector, claim 20 has been amended to recite an adenoviral vector encoding CTLA4Ig. With regard to enablement for a method comprising incubating said isolated tolerogenic dendritic cells in the presence of one or more cytokines, claim 17 has been amended to recite the cytokine as GM-CSF. Accordingly, claim 18 has been cancelled.

For the foregoing reasons, applicants submit that the specification provides sufficient enablement for the pending claims, as amended. Therefore, applicants respectfully request the

withdrawal of the rejection of claims 4-6, 12-14, 15 and 17-29 and 32-34 under 35 U.S.C. § 112, first paragraph.

The Rejections under 35 U.S.C. § 112, ¶2 Should Be Withdrawn

The Examiner has rejected claims 1, 2, 4-7, 9-15, 17-30 and 32-34 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 1, 7, 15, 17 and 30 recite the phrase "wherein the NFκB binding sites inhibit NFκB transcriptional activity."

In response, claims 1, 7, 15, 30 have been amended to replace the cited phrase with "wherein the oligodeoxyribonucleotide inhibits NF-κB transcriptional activity." Support for this amendment can be found throughout the specification and in particular at page 14, para. 00041 and Example 7, pp. 34-35. Applicants submit that the present amendment does not alter the subject matter of the claims. Since the cited phrase was inserted in response to a patentability rejection under 35 U.S.C. § 103(a), Applicants further submit that the claims, as amended, are patentable over the art cited in the Office Action mailed December 4, 2002, *i.e.* Storm et al. (US 2002/0164311 A1) in further view of Thomson et al. (US 5,871,728), Lu et al.$_1$ (Journal of Leukocyte Biology), Lu et al.$_2$ (Gene Therapy), and Bielinska et al.

The Examiner has also rejected claims 9 and 17 as being indefinite because they recite the phrase "the presence of one or more cytokine." In accordance with the Examiner's suggestion, claims 9 and 17 have been amended to recite this phrase with the following phrase

"the presence of one or more cytokine(s)." Therefore, applicants respectfully request the withdrawal of the rejection of claims 41, 2, 4-7, 9-15, 17-30 and 32-34 under 35 U.S.C. § 112, second paragraph.

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request withdrawal of the outstanding rejections and allowance of the pending claims.

Applicants do not believe that any fee is required in connection with the submission of this document. However, should any fee be required, or if any overpayment has been made, the Commissioner is hereby authorized to charge any fees, or credit or any overpayments made, to Deposit Account 02-4377. A duplicate copy of this sheet is enclosed.

Respectfully submitted,
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